

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
12-15	C4591001 1006 10061212	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061220	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061227	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061248	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061261	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061280	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061282	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071467	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071471	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071523	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1007 10071574	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1008 10081764	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1008 10081800	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091221	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091265	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091280	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091281	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091288	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091354	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

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Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1013 10131822	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131828	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131841	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131850	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131855	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1016 10161334	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1016 10161338	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1016 10161356	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1039 10391269	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

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Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1044 10441276	Dose 2 evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1044 10441295	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571378	Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571396	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571399	Dose 2 evaluable	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571400	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571409	Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571412	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1066 10661408	Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1066 10661417	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

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Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1077 10771274	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1077 10771288	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1091 10911413	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231431	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231432	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231438	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231439	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231440	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231441	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

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Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1123 11231448	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1124 11241249	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1126 11261269	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1126 11261277	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1131 11311275	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1139 11391151	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1139 11391156	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1139 11391170	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1140 11401336	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1140 11401337	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

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Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1142 11421319	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1142 11421330	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1142 11421343	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1147 11471274	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1150 11501119	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1150 11501129	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521625	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521640	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521641	Dose 2 all- available	Did not receive Dose 2.
		Dose 2 evaluable	Did not receive 2 doses of the vaccine to which they were randomly assigned.

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Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1152 11521645	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521656	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521657	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521661	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521667	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521679	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521683	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521684	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521686	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521689	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

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Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1152 11521697	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561257	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561304	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561311	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561321	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561324	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1235 12351246	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1270 12701177	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1270 12701187	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

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Age Group (Years)	Subject	Population	Reason for Exclusion
16-25	C4591001 1006 10061137	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061159	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071434	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071447	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071454	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071473	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1008 10081743	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091210	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091235	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1011 10111213	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

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Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131059	Dose 2 evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1013 10131276	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131653	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131763	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131817	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131829	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131834	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1015 10151150	Dose 2 evaluable Dose 2 all- available	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1018 10181032	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

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Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1046 10461346	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1047 10471275	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1047 10471306	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1056 10561171	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1056 10561392	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1057 10571217	Dose 2 evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1057 10571366	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571368	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1068 10681119	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.

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Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1079 10791162	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1080 10801055	Dose 2 evaluable	Had important protocol deviation(s) as determined by the clinician.
	C4591001 1080 10801179	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1082 10821036	Dose 2 evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1084 10841423	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1085 10851373	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1087 10871565	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1088 10881200	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1090 10901328	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1091 10911389	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1091 10911391	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1092 10921146	Dose 2 evaluable Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1093 10931174	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1093 10931203	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1095 10951271	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1095 10951310	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1096 10961032	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1096 10961196	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1096 10961392	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1098 10981177	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1109 11091391	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1109 11091532	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1111 11111183	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1112 11121260	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1114 11141021	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1116 11161320	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1116 11161322	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1120 11201337	Dose 2 evaluable	Did not have blood collection within 28-42 days after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1123 11231416	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231417	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231429	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231430	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1125 11251240	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1126 11261231	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1126 11261234	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1131 11311064	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1131 11311268	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1133 11331609	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1135 11351239	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1135 11351323	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1135 11351461	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1135 11351492	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1135 11351497	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1135 11351556	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1139 11391132	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1140 11401316	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1141 11411006	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1141 11411269	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1142 11421338	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1147 11471260	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1149 11491079	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1149 11491302	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1150 11501016	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1150 11501188	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521115	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521451	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521464	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1152 11521632	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561203	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561288	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561329	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1162 11621479	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1168 11681069	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1170 11701089	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1170 11701392	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1170 11701419	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1171 11711211	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1171 11711221	Dose 2 evaluable Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not receive Dose 2 within 19-42 days after Dose 1.
	C4591001 1177 11771540	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1204 12041144	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1204 12041275	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1218 12181047	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1220 12201015	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1221 12211036	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1224 12241183	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1224 12241187	Dose 2 evaluable Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1232 12321302	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1235 12351014	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1235 12351230	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1254 12541121	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1254 12541178	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1258 12581069	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1264 12641095	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1270 12701195	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 28MAR2021 (12:59) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_1001_excl_ped_eval			

16.2.3.2.1 Listing of Subjects Excluded From Safety Population – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	Reason for Exclusion
12-15	C4591001 1057 10571413	Subject did not receive study vaccine.
	C4591001 1077 10771293	Subject did not receive study vaccine.
	C4591001 1091 10911451	Subject did not receive study vaccine.
	C4591001 1140 11401346	Subject did not receive study vaccine.
16-25	C4591001 1013 10131740	Subject did not receive study vaccine.
	C4591001 1057 10571211	Subject did not receive study vaccine.
	C4591001 1092 10921128	Subject did not receive study vaccine.
	C4591001 1093 10931055	Subject did not receive study vaccine.
	C4591001 1112 11121229	Subject did not receive study vaccine.
	C4591001 1120 11201038	Subject did not receive study vaccine.
	C4591001 1122 11221026	Subject did not receive study vaccine.
	C4591001 1123 11231027	Subject did not receive study vaccine.
	C4591001 1129 11291048	Subject did not receive study vaccine.
	C4591001 1161 11611006	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611015	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611016	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611018	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611019	Unreliable data due to lack of PI oversight.
	C4591001 1224 12241170	Subject did not receive study vaccine.
	C4591001 1231 12313443	Subject did not receive study vaccine.
	C4591001 1231 12313527	Subject did not receive study vaccine.
	C4591001 1248 12481025	Subject did not receive study vaccine.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:37)
 (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_l001_excl_ped_saf_all

090177e196ac9159\Final\Final On: 31-Mar-2021 13:05 (GMT)

16.2.3.2.2 Listing of Subjects Excluded From Safety Population – Phase 2/3 Subjects 16-55 Years of Age		
Age Group (Years)	Subject	Reason for Exclusion
16-55	C4591001 1003 10031140	Subject did not receive study vaccine.
	C4591001 1003 10031143	Subject did not receive study vaccine.
	C4591001 1005 10051381	Subject did not receive study vaccine.
	C4591001 1013 10131017	Subject did not receive study vaccine.
	C4591001 1013 10131740	Subject did not receive study vaccine.
	C4591001 1036 10361050	Subject did not receive study vaccine.
	C4591001 1057 10571031	Subject did not receive study vaccine.
	C4591001 1057 10571211	Subject did not receive study vaccine.
	C4591001 1057 10571212	Subject did not receive study vaccine.
	C4591001 1057 10571215	Subject did not receive study vaccine.
	C4591001 1057 10571268	Subject did not receive study vaccine.
	C4591001 1066 10661335	Subject did not receive study vaccine.
	C4591001 1071 10711162	Subject did not receive study vaccine.
	C4591001 1081 10811105	Subject did not receive study vaccine.
	C4591001 1082 10821013	Subject did not receive study vaccine.
	C4591001 1089 10891346	Subject did not receive study vaccine.
	C4591001 1089 10891351	Subject did not receive study vaccine.
	C4591001 1092 10921128	Subject did not receive study vaccine.
	C4591001 1093 10931055	Subject did not receive study vaccine.
	C4591001 1109 11091349	Subject did not receive study vaccine.
	C4591001 1112 11121229	Subject did not receive study vaccine.
	C4591001 1116 11161015	Subject did not receive study vaccine.
	C4591001 1120 11201038	Subject did not receive study vaccine.
	C4591001 1120 11201252	Subject did not receive study vaccine.
	C4591001 1122 11221006	Subject did not receive study vaccine.
	C4591001 1122 11221026	Subject did not receive study vaccine.
	C4591001 1123 11231027	Subject did not receive study vaccine.
	C4591001 1123 11231301	Subject did not receive study vaccine.
	C4591001 1126 11261074	Subject did not receive study vaccine.
	C4591001 1129 11291048	Subject did not receive study vaccine.

16.2.3.2.2 Listing of Subjects Excluded From Safety Population – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)	Subject	Reason for Exclusion
	C4591001 1133 11331162	Subject did not receive study vaccine.
	C4591001 1135 11351389	Subject did not receive study vaccine.
	C4591001 1149 11491108	Subject did not receive study vaccine.
	C4591001 1161 11611002	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611005	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611006	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611011	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611015	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611016	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611018	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611019	Unreliable data due to lack of PI oversight.
	C4591001 1162 11621024	Subject did not receive study vaccine.
	C4591001 1162 11621477	Subject did not receive study vaccine.
	C4591001 1167 11671003	Subject did not receive study vaccine.
	C4591001 1168 11681030	Subject did not receive study vaccine.
	C4591001 1205 12051028	Subject did not receive study vaccine.
	C4591001 1212 12121023	Subject did not receive study vaccine.
	C4591001 1223 12231200	Subject did not receive study vaccine.
	C4591001 1223 12231234	Subject did not receive study vaccine.
	C4591001 1224 12241170	Subject did not receive study vaccine.
	C4591001 1231 12311409	Subject did not receive study vaccine.
	C4591001 1231 12311516	Subject did not receive study vaccine.
	C4591001 1231 12311926	Subject did not receive study vaccine.
	C4591001 1231 12312176	Subject did not receive study vaccine.
	C4591001 1231 12312483	Subject did not receive study vaccine.
	C4591001 1231 12313443	Subject did not receive study vaccine.
	C4591001 1231 12313527	Subject did not receive study vaccine.
	C4591001 1231 12313869	Subject did not receive study vaccine.
	C4591001 1231 12314738	Subject did not receive study vaccine.
	C4591001 1231 12315308	Subject did not receive study vaccine.

16.2.3.2.2 Listing of Subjects Excluded From Safety Population – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)	Subject	Reason for Exclusion
	C4591001 1232 12321037	Subject did not receive study vaccine.
	C4591001 1235 12351167	Subject did not receive study vaccine.
	C4591001 1248 12481018	Subject did not receive study vaccine.
	C4591001 1248 12481025	Subject did not receive study vaccine.
	C4591001 1248 12481060	Subject did not receive study vaccine.
	C4591001 1248 12481218	Subject did not receive study vaccine.
	C4591001 1251 12511204	Subject did not receive study vaccine.
	C4591001 1260 12601049	Subject did not receive study vaccine.
	C4591001 1260 12601070	Subject did not receive study vaccine.
	C4591001 1264 12641018	Subject did not receive study vaccine.
	C4591001 4444 44441135	Subject did not receive study vaccine.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 30MAR2021 (13:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001 EUA 1655/adsl 1001 excl saf 1655